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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,030	11/17/2003	Alain Friboulet	16773-002001 / B4852AF-AD	5572

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EXAMINER	
HARLE, JENNIFER I	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary	Application No.	Applicant(s)	
	10/716,030	FRIBOULET ET AL.	
	Examiner	Art Unit	
	Jennifer I. Harle	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *4-8 and 13-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-3 and 9-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 4-8, and 13-23 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). However, the examiner has placed the claims in the groupings based upon the broadest claim and the specific compound. Applicant is hereby requested to correct the errors or these claims will not be treated on the merits in the next Official Action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 7-9 (in part), drawn to a substrate of an enzyme or an analogue thereof, inhibitor or activator, which is capable of modulating the activity of a catalytic antibody characterized in that it has a specific affinity for the catalytic site of the antibody and is non immunogenic, classified in class 514, subclass 2+.

II. Claims 1-3 (in part), 5-6, drawn to a ligand binding itself to a receptor or a fragment or an analogue thereof, which is capable of modulating the activity of a catalytic antibody characterized in that it has a specific affinity for the catalytic site of the antibody and is non immunogenic, classified in class 514, subclass 2+.

III. Claims 1-3 (in part), drawn to an antibiotic or an analogue thereof, which is capable of modulating the activity of a catalytic antibody characterized in that it has a specific affinity for the catalytic site of the antibody and is non immunogenic, classified in class 514, subclass 2+.

IV. Claims 1-3 (in part), 4, drawn to a viral peptide, which is capable of modulating the activity of a catalytic antibody characterized in that it has a specific affinity

for the catalytic site of the antibody and is non immunogenic, classified in class 514, subclass 2+.

V. Claims 1-3 (in part), drawn to a bacterial peptide, which is capable of modulating the activity of a catalytic antibody characterized in that it has a specific affinity for the catalytic site of the antibody and is non immunogenic, classified in class 514, subclass 2+.

VI. Claims 1-3 (in part), drawn to a parasitic peptide, which is capable of modulating the activity of a catalytic antibody characterized in that it has a specific affinity for the catalytic site of the antibody and is non immunogenic, classified in class 514, subclass 2+.

VII. Claims 1-3, 10 (in part), drawn to a recalcitrant and potentially toxic xenobiotic or a fragment thereof, which is capable of modulating the activity of a catalytic antibody characterized in that it has a specific affinity for the catalytic site of the antibody and is non immunogenic, classified in multiple classifications.

VIII. Claims 1-3 (in part), 12, drawn to drawn to an allergen analogue, which is capable of modulating the activity of a catalytic antibody characterized in that it has a specific affinity for the catalytic site of the antibody and is non immunogenic, classified in class 514, subclass 2+.

IX. Claim 13, drawn to use of a substrate of an enzyme of an analogue thereof, inhibitor or activator in preparing a pharmaceutical composition for the treatment or prevention of a disease linked to an enzymatic deficiency, classified in class 514, subclass 2+.

X. Claim 15, drawn to use of an allergen analogue in preparing a pharmaceutical composition for preventing or desensitizing against allergic reactions, classified in class 514, subclass 2+.

XI. Claims 16-21, drawn to a method for selecting a compound, wherein the compound is a substrate of an enzyme or an analogue thereof, inhibitor or activator, by selecting and isolating a natural catalytic antibody or a catalytic antibody induced by repeated injection of an immunogenic molecule, classified in class 435, subclass 7.1.

XII. Claims 16-21, drawn to a method for selecting a compound, wherein the compound is a ligand binding itself to a receptor, especially a hormone a drug, a medication or a fragment or an analogue thereof, by selecting and isolating a natural catalytic antibody or a catalytic antibody induced by repeated injection of an immunogenic molecule, classified in class 435, subclass 7.1.

XIII. Claims 16-21 (in part), drawn to a method for selecting a compound, wherein the compound is an antibiotic or an analogue thereof, by selecting and isolating a natural catalytic antibody or a catalytic antibody induced by repeated injection of an immunogenic molecule, classified in class 435, subclass 7.1.

XIV. Claims 16-21, drawn to a method for selecting a compound, wherein the compound is a viral peptide, by selecting and isolating a natural catalytic antibody or a catalytic antibody induced by repeated injection of an immunogenic molecule, classified in class 435, subclass 7.1.

XV. Claims 16-21 (in part), drawn to drawn to a method for selecting a compound, wherein the compound is a bacterial peptide, by selecting and isolating a natural catalytic antibody or a catalytic antibody induced by repeated injection of an immunogenic molecule, classified in class 435, subclass 7.1.

XVI. Claims 16-21 (in part), drawn to a method for selecting a compound, wherein the compound is a parasitic peptide, by selecting and isolating a natural catalytic antibody or a catalytic antibody induced by repeated injection of an immunogenic molecule, classified in class 435, subclass 7.1.

XVII. Claims 16-21 (in part), drawn to a method for selecting a compound, wherein the compound is a recalcitrant and potentially toxic xenobiotic or a fragment thereof, by selecting and isolating a natural catalytic antibody or a catalytic antibody induced by repeated injection of an immunogenic molecule, classified in class 435, subclass 7.1.

XVIII. Claims 16-21 (in part), drawn to drawn to a method for selecting a compound, wherein the compound is an allergen analogue, by selecting and isolating a natural catalytic antibody or a catalytic antibody induced by repeated injection of an immunogenic molecule, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The Specification does not show any of Groups 1-VIII capable of use together. In the instant case the different inventions

they have different modes of operation, different functions or effects. For example substrate of an enzyme can digest peptides, a ligand can bind to a receptor can be used in conjunction with their distances to compare the results of simulations with crystal structures, an antibiotic can be used in the livestock feed industry to promote growth of the livestock, a viral peptide can be used to create a vaccine, a bacterial peptide can be used to create products that protect plants against bacteria, a parasitic peptide can be used to create insecticides, a recalcitrant and potentially toxic xenobiotic can be used to study metabolic pathways and an allergen analogue can be used as a mechanism to design other allergen analogues. Assusming arguendo that the inventions are distinct, as set forth above each group has a utility by itself and does not require the particulars of any of the others for patentability, as each compound does not have a core structure required of any of the others.

Inventions I-VIII and IX are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I-VIII each have the separate utility as set forth above. See MPEP § 806.05(d).

Inventions I-VIII and X are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I-VIII each has the separate utility as set forth above. See MPEP § 806.05(d).

Inventions I-VIII and XI-XVIII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are

shown to be separately usable. In the instant case, invention I-VIII each have the separate utility as set forth above. See MPEP § 806.05(d).

Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation, functions and effects in that Group IX is directed specifically toward diseases linked to an enzymatic deficiency, i.e. dysmyelinating diseases such as ALD are inherited enzymatic deficiencies, whereas Group X is directed to preventing or desensitizing against allergic reactions, dust, mold, bee stings.

Inventions IX and XI-XVIII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention IX has separate utility such as preparing a pharmaceutical to treat or prevent ALD for use in a human, whereas XI-XVIII is merely an assay/screening for prospective compounds and does not reach the level of a therapeutic but merely whether the compounds react with a catalytic site of the antibody. See MPEP § 806.05(d).

Inventions X and XI-XVIII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention X has separate utility such as preparing a pharmaceutical to preventing or desensitizing against allergic reactions, dust, mold, bee stings for use in a human, whereas XI-XVIII is merely an assay/screening for prospective compounds

and does not reach the level of a therapeutic but merely whether the compounds react with a catalytic site of the antibody. See MPEP § 806.05(d).

Inventions XI-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions or effects because they utilize the same compounds of Groups I-VIII. For example substrate of an enzyme can digest peptides, a ligand can bind to a receptor can be used in conjunction with their distances to compare the results of simulations with crystal structures, an antibiotic can be used in the livestock feed industry to promote growth of the livestock, a viral peptide can be used to create a vaccine, a bacterial peptide can be used to create products that protect plants against bacteria, a parasitic peptide can be used to create insecticides, a recalcitrant and potentially toxic xenobiotic can be used to study metabolic pathways and an allergen analogue can be used as a mechanism to design other allergen analogues. Assusming arguendo that the inventions are distinct, as set forth above each group has a utility by itself and does not require the particulars of any of the others for patentability, as each compound does not have a core structure required of any of the others.

Because these inventions are distinct for the reasons given above and the search required for each Group is not required for the other restriction for examination purposes as indicated is proper. The searches are divergent because the automation searching requires literature, patent, and internet, as well as, structure and/or sequence searches of multiple databases with multiple synonyms and key word searches.

The invention is drawn to many different components, which are contained in many different compositions. Dependant claims are drawn to specific components. The components vary distinctly in their structures and functions. Thus, an individual search is required of each individual component. Therefore, as part of selecting one of the groups as the elected invention, Applicant is required to select a specific composition containing the elected components, to which the elected invention will be examined on the merits as drawn to; as well as identifying those claims to which the elected composition is drawn. This requirement is not to be taken as an election of species, but rather as a selection of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Additionally, claims 17 and 18 generic to a plurality of disclosed patentably distinct methods for deriving the immunogenic molecules/peptides comprising combinatorial chemistry, biosynthesis, bioconversion, or mutagenesis of a DNA. If Applicant elects Groups XII-XVIII, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Moreover, because claim 11, 14, 22-23 are broad and reads upon literally a plethora of unknown compounds and reads upon multiple groups, it will only be examined in light of the elected group and compound and species. If any claim(s) is/are eventually found to be

allowable, claims 11, 14 and 22-23 must be amended to fit within the scope of the elected and allowable subjected matter.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Ione Harle
August 3, 2004

MICHAEL MELLER
PRIMARY EXAMINER